Remarks/Arguments:

With the present response, claims 1, 3-8, 10, 11, 17, 30-33, 47, and 51 are pending.

Claim rejections under 35 U.S.C. §103

Claims 1, 3-8, 10, 11, 17, 30, 32, 47, and 51 stand rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5, 201,757 to Heyn et al. ("Heyn") in view of U.S. Patent No. 6,042,589 to Marianne ("Marianne"). Applicants respectfully traverse this rejection.

Rejection of independent claim 1

Claim 1 recites, *inter alia*, an introducer, having a retrograde portion and an anterograde portion, for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration. The introducer comprises a shaft having a distal tip, an inner sheath mounted concentrically over the shaft, wherein the endoluminal device is mounted concentrically over the inner sheath in the compressed configuration, and an anterograde sheath attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer. The anterograde sheath has an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder. The introducer further includes *anchoring means* in at least one of the retrograde portion or the anterograde portion *for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen and for minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end*. Emphasis added.

The Office Action discounts the above claim limitation as reciting an "intended use." The applicant respectfully points out that the above is clearly means-plus-function language and therefore must be treated as a structural limitation -- only structures capable of performing the claimed function read upon the claimed invention. The Applicants respectfully submit that neither of the cited references teach structures capable of performing the claimed function, nor would the references, if combined despite the lack of motivation to make such a combination, result in such a structure.

Heyn teaches a medial-region-first stent deployment device with the inclusion of "detents" to "prevent any substantial axial travel of the stent relative to the intermediate catheter" underlying the stent. Heyn, col. 6, lines 50-54. Heyn teaches, generally, that during deployment of a self-expanding stent, outer distal and proximal sleeves are axially retracted to release its stent. The detents function passively to prevent the stent from migrating axially in response to friction between the stent and the outer sleeves during retraction of the sleeves. Once the outer sleeves are fully retracted, the stent is deployed. The detents taught by Heyn do not, indeed cannot, anchor the proximal end of its stent **after expansion of the proximal end** because the detents are located *within* Heyn's catheter body and contact the stent only in the compressed configuration. Once the proximal end of Heyn's stent is deployed, it has exited Heyn's delivery device and is no longer in contact with the detents. Accordingly, Heyn's detents are incapable of performing the first function that defines of Applicants' anchoring means - "anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration in the body lumen." Furthermore, one skilled in the art, looking at Heyn's device including its detents, would not be motivated to adapt Heyn to achieve Applicants' anchoring means feature because Heyn is silent with respect to fixing the end of a stent after its expansion into the body lumen.

Likewise, Heyn's detents cannot perform the second function that defines the structure of Applicants' anchoring means, which is to minimize relative axial movement *between the proximal end of its endoluminal device and the body lumen* during the stent's deployment. As Heyn explicitly states, the sole function of its detents is to "prevent any substantial axial travel of the stent *relative to the intermediate catheter*." The detents of Heyn are incapable of minimizing relative axial movement of its stent with respect to the body lumen because they are located entirely within the catheter and cannot exert any force on the stent end once that end has been deployed in the expanded state. Not only does Heyn fail to teach this function, it fails to even suggest it. Heyn is silent with respect to minimizing movement of the stent *relative to the body lumen* and so would provide no suggestion or motivation to arrive at Applicants' anchoring means.

Marianne discloses teaches a traditional, distal-end first, stent deployment device equipped with a "micro-balloon" that can be inflated to pin its stent *against the inner surface of its outer sheath*. Marianne, Fig 3. Marianne teaches that this ability to fix the stent against the inner sheath permits an implanting surgeon to recapture the stent by pulling back on the underlying inner tube and urging it back into the catheter. Marianne, col. 3, lines 25-38.

Marianne teaches principal use of its balloon 20 by slight inflation "causing the proximal end of the stent 7 to be firmly locked in place with respect to the inner tube 8" of the device. *See* Marianne, col. 3, lines 5-9. Like Heyn, this deployment use taught by Marianne also fixes the *unexpanded* stent portion *inside* the deployment device and *against the inner surface* of its inner tube. *See* Marianne Fig. 2. Marianne also discloses secondary uses for its micro-balloon whereby (1) its additional friction is used hold the stent in place relative to the deployment device while dragging the entire apparatus in a proximal direction should some error occur during initial placement of the stent (col. 3, lines 28-34) or (2) as a traditional dilatation balloon to expand the stent fully against resistance posed by a stenosis (col. 3, lines 45-53). Marianne does not teach or suggest the use of its balloon as an "anchoring means" to fix an *expanded* stent portion *outside* the deployment device *against the body lumen* during unsheathing of a remaining portion of the endoluminal device distal of the proximal end, nor could it be used in such a manner.

Marianne's description of a balloon does not suggest Applicants' anchoring means either, because Marianne does not teach a structure for minimizing the relative axial movement *between the proximal end of an endoluminal device and the body lumen*. Marianne is silent on this structure.

Thus, Marianne teaches a structure for fixing the unexpanded end of the stent *against the outer sheath* and Heyn teaches a structure for limiting travel of the unexpanded end of the stent *with respect to the inner, intermediate catheter*, whereas Applicants' invention claims a structure in the form of means for minimizing movement of the stent *with respect to the treated body lumen*. The three approaches and the structures used for each of the three approaches are therefore disparate.

Further, the Office Action states that "Heyn includes all of the limitations of the claimed invention, but fails to form the anchoring means as a balloon." Office Action, page 3 lines 1-2. The Office Action further states that "Marianne discloses a stent (7) introducer with a retracting sheath (16) and a proximal anchoring means in the form of a balloon (20). Office Action, page 3, lines 2-3. The Office Action makes a conclusion that "[s]imilar to the anchor (104) of Heyn, the balloon prevents axial movement of the stent during retraction of the sheath for deployment" and that "[i]n this way, the detent of Heyn and the balloon of Marianne are functionally equivalent." Office Action, page 3, lines 4-6.

The Office Action further asserts that it would have been obvious "to replace the

anchoring detent of Heyn with a balloon, as taught by Marianne." Office Action, page 3, lines 9-11. Motivation to combine the references must be shown. *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998); *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Moreover, "[t]he showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence." *Teleflex, Inc. v. Ficosa North Am. Corp.*, 63 USPQ2d 1374 (Fed. Cir. 2002). Marianne does not teach or suggest a motivation to modify Heyn, because Marianne's teachings to pin its stent against its outer sheath are at odds with Heyn's focus on fixing its own stent with respect to its inner, intermediate catheter. Marianne's teachings are even more incompatible with Heyn's explicit interest in ensuring that the outer sheaths of its device move freely and easily. Heyn, col. 5, line 63 - col. 6, line 5. Heyn's proximal and distal sheaths will not move freely and easily with one or more balloons exerting radial force(s) against them as taught by Marianne. Applicants respectfully submit that there is no motivation to combine Heyn and Marianne as suggested in the Office Action to arrive at the claimed invention.

Although Applicants disagree with the Office Action assertion that it would have been obvious "to replace the anchoring detent of Heyn with a balloon, as taught by Marianne", the following analysis explores the resulting structure if such a replacement were made. Marianne teaches only balloon embodiments in which the balloon is in some way fixed relative to inner tube 8. *See* col. 3, lines 55-57: "the pressure required to inflate the micro-balloon 20 is exerted by a fluid carried along a second lumen 22 extending along the axial lumen 4 of the inner tube 8." (Figs. 1-4); col. 4, lines 14-16: "the balloon 20 is fixed at its distal end to the inner tube 8" (Fig. 5); and col. 4, lines 18-19: "inner tube 8 encloses two separated lumens . . ." (Fig. 6). Furthermore, tip 10 is also attached to inner tube 8. Thus, Marianne teaches a balloon having a location fixed relative to tip 10 and inner tube 8.

The Office Action, however, states it is obvious "to replace the anchoring detent of Heyn with a balloon, as taught by Marianne, in order to provide the user with the added capabilities of repositioning the stent and dilating the vessel without changing catheters." Office Action, page 3, lines 10-13.

Nowhere, however, does Marianne teach or suggest how to use an inner sheath as an inflation lumen where the inner sheath surrounds an inner tube that is *movable* relative to the inner sheath, as is present in the embodiment shown and described with respect to Figs. 2 and 4 of Heyn. In all embodiments taught by Marianne, the inner sheath and the inner tube are fixed relative to one another, whereas in Heyn, the analogous elements are movable relative to

one another. Such relative movability is required to perform the claimed limitation of anchoring the proximal end of the stent while the distal portion is unsheathed, given that the inner tube (connected to the tip) must be advanced distally in order to advance the anterograde sheath covering the distal portion of the stent. Were the balloon fixed relative to that inner tube, it would move the stent axially in concert with the anterograde sheath, thus defeating the limitation of minimizing relative movement between the stent and the body lumen.

Thus, Applicants respectfully submit that modifying Heyn to provide a workable balloon therefore requires more than a simple combination of Heyn and Marianne. Merely providing a balloon fixed relative to the inner tube as is shown in Marianne would be unworkable, as described above. Rather, a workable balloon adapted to the Heyn design would require an inner sheath design that allows relative motion between the inner sheath and the inner core, while still providing a sealed lumen for communicating fluid to the balloon. Such an inner sheath design is outside the scope of what is taught either by Heyn or Marianne, and, in fact, would require the design taught by Applicants. Because the combination of the cited references does not provide sufficient disclosure to create the structure required to meet all of the claimed limitations, Applicants submit that the combination fails to disclose all of the limitations of claim 1.

In summary, the Office Action has advanced no credible suggestion or motivation for either reference to adopt or be combined with the structure disclosed in the other reference to arrive at Applicants' invention as claimed. Specifically, there is no suggestion to combine features of a medial-region-first stent deployment device having an internal detents as taught by Heyn with a deployment device having a balloon as taught by Marianne, nor do the cited references provide adequate disclosure to create a structure capable of meeting all of the claimed limitations.

For at least the reasons recited above, Applicants respectfully submit that the rejection of claim 1 is improper and respectfully request reconsideration and allowance of the claim. Claims 3-8, 10, 11, 17, 30-33, and 51 all ultimately depend from claim 1 and Applicants respectfully submit that these claims are patentable over the cited prior art for at least the same reasons as set forth above with respect to claim 1. Applicants respectfully request reconsideration and allowance of claims 3-8, 10, 11, 17, 30-33, and 51.

Rejection of independent claim 47

Claim 47 recites, *inter alia*, an introducer for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration. The introducer comprises a retrograde portion and an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer. The anterograde sheath has an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder. A shaft is attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion. An endoluminal device is mounted concentrically over the shaft in the central lumen and having a distal portion contained by the anterograde portion and a proximal end contained by the retrograde portion. The distal portion is constrained in the compressed configuration by the anterograde sheath and adapted to expand into an expanded state as the anterograde sheath is advanced distally. *An inflatable balloon is mounted radially inside the retrograde portion and sized to anchor the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration to minimize relative axial movement between the proximal end of the device and the body lumen during unsheathing of the endoluminal device distal portion*. Emphasis added.

Rather than reciting the "anchoring means" of claim 1, claim 47 recites *"an inflatable balloon . . . sized to anchor the endoluminal device proximal end against the body lumen."* Marianne is cited for its inflating balloon. Applicants repeat the arguments made above against the proposed combination with respect to claim 1. Applicants respectfully submit that claim 47 is patentable over the cited prior art for the same reasons as set forth above with respect to claim 1. Reconsideration and allowance of claim 47 is respectfully requested.

Rejection of claims 31 and 33

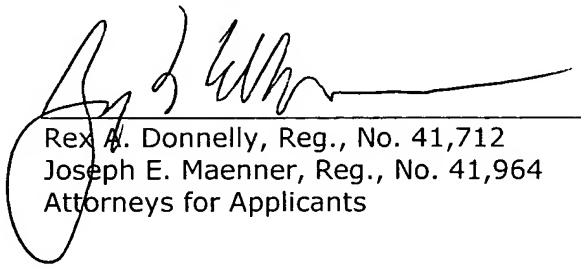
Claims 31 and 33 stand rejected under 35 U.S.C. §103(a) as unpatentable over Heyn in view of Marianne, and further in view of U.S. Patent No. 5,445,646 to Eutereuer. Claims 31 and 33 both ultimately depend from claim 1, and Applicants respectfully submit that claims 31 and 33 are patentable over the cited prior art for at least the same reasons as set forth above with

respect to claim 1. Reconsideration and allowance of claims 31 and 33 is respectfully requested.

Conclusion

In light of the above arguments, Applicants respectfully submit that the present application is in condition for allowance. Prompt reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,



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